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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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WOODCOCK WASHBURN LLP  
ONE LIBERTY PLACE, 46TH FLOOR  
1650 MARKET STREET  
PHILADELPHIA, PA 19103

EXAMINER

BORIN, MICHAEL L

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 12/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/580,491

Applicant(s)

HERTOGS ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/27/2004 has been entered.

2. Claim 7 is pending. The claim has been amended to recite, first, determining all three of the recited types of mutations related to three types of HIV reverse transcriptase and protease inhibitors, and second, to recite particular NRTI, NNRTI, and PI inhibitors (step d).

3. Applicants arguments with respect to rejections of record made are noted but are deemed moot in view of the new grounds of rejection. The following rejections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

***Claim Rejections - 35 USC § 103***

4. Claim 7 is under 35 U.S.C. 103(a) as being unpatentable over Condra et al., and admitted prior art, and Seki et al. (Antiviral Chemistry & Chemotherapy (1995) 6(2), 73-9), and Bakhanashvili et al (FEBS Letters (1996), 391(3), 257-262).

Condra reference has been used in the prior art rejection under 35 U.S.C. 102(b) throughout preceding prosecution history. The reference addresses issues of resistance of HIV treatment to indinavir, HIV protease inhibitor. The reference evaluates effectiveness of antiviral therapy of HIV patients with protease inhibitor Indinavir (IDV). To evaluate the effectiveness of therapy with IDV, blood of HIV infected patients was collected (same step as step I) of the instant claim), and nucleic acids encoding HIV protease are examined (i.e., as in step (ii)(c) of claim 7. In one patient, patient "O" at least one mutation, namely 88T (i.e., the elected species) correlates with reduced effectiveness of antiviral therapy (see table 1, patient "O") - the resistance to IDV increased to over 3000 nM (see table 1, column IDV CIC and p. 8270, right col., lines 9-10 from bottom). The thus identified at least one mutation correlates with reduced effectiveness of IDV (which reads on step (iii) of the instant claim. Note, that even though the instant claim 7, step c), recites various mutations, it is drawn to "at least one" mutation, and,

therefore, it reads on situations wherein the recited mutation is one of several others.

Condra et al do not teach address resistance conferred by mutations in HIV reverse transcriptase as it addresses treatment with a protease inhibitor alone. However as well accepted in the art, and as addressed in the Background section, p. 3, last full paragraph, the preferential HIV therapy includes combination of inhibitors of both PI and RT (reverse transcriptase), the latter can be also a combination of NNRTI and NRTI. Therefore, it would be obvious to one skilled in the art at the time the invention made to evaluate effectiveness of such combined anti-HIV therapy by determining presence of potential resistance to RT inhibitors. In regard to the latter, Seki et al teach that resistance to NNRTIs is dependent on both the quality and the quantity of mutations within the HIV-1 RT gene, and, in particular point at mutation at 103 position to 103R which is related to development of the resistance (compare to claim 7, step (a)(2)). Further, Bakhanashvili et al (see p. 262, last full paragraph, p. 261, right column, first full paragraph) teach resistance to treatment by nucleoside analogs conferred by Met 184 to Leu mutation in RT, i.e., another mutation addressed in the instant claim.

Taken together, an artisan would be motivated to evaluate effectiveness of anti-HIV therapy by determining presence of potential resistances to both PI and RT inhibitors, i.e., inhibitors used in combination as a part of routine HIV therapy . In the course of assessing potential mutations, an artisan would be motivated to

Art Unit: 1631

determined to mutations described in Condra, Seki and Bakhanashvili as these mutations are some of the mutations conferring resistance to known HIV PI or RT inhibitors.

***Claim Rejections - 35 USC § 112, first paragraph.***

5. The enablement rejection of claim 7 under 35 U.S.C. 112, first paragraph, is withdrawn in view of applicant's arguments.

6. The following written description is deemed necessary in view of amendment to claim 7 (step d)).

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claim 7 is amended to specify subgenus of inhibitors- see step d). The examiner has not found *ipsis verbis* support for such limited subgenus in the specification, nor has applicant indicated support in the specification for the subgenus as claimed. Pages 20, 28 referenced by applicant are generic to any RT or protease inhibitor and do not describe the subgenus as now claimed. Applicant must cancel the new matter in response to this rejection.

Art Unit: 1631

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571)272-0713. The examiner can normally be reached on 9 am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-0722. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Borin  
Primary Examiner  
Art Unit 1631

12/02/04